REMARKS

Claims 1-11 and 14-43 are pending; claims 3, 10, 11, 16-28 and 34-37 are withdrawn from consideration. Reconsideration of the claims is respectfully requested, in light of the following remarks.

The Examiner has rejected claims 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39 and 41-43 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,726,923 to Lyer, et al. (hereafter "Lyer"). The rejection is respectfully traversed.

To maintain a 35 U.S.C. §102(e) rejection, a single reference must teach each and every element of a claim. Lyer fails to do so.

Claim 1 recites a device for creating an anastomosis between first and second blood vessels. The device includes an extravascular body, a first securing means and a second securing means. The extravascular body includes an outer surface and an inner surface. The outer surface forms the outer profile of the body and the inner surface forms an opening configured to contact a portion of the first vessel received therein. The first securing means adhesively secures at least an end of the first vessel to the opening. The second securing means secures a portion of the second vessel to a corresponding portion of the outer surface of the extravascular body such that a hole formed in the portion of the second vessel is in fluid communication with the first vessel.

Claim 29 recites a method for creating an anastomosis between first and second blood vessels. The method includes adhesively attaching a portion of the first vessel to an extravascular body. The extravascular body comprises an opening therethrough. The opening is configured to receive and contact the portion of the first vessel. The extravascular body further

comprises an outer surface, which forms the outer profile of the body and at least a portion of which is configured to contact a portion of the second vessel. The method further includes attaching the portion of the second vessel to the corresponding portion of the outer surface of the body, and creating an anastomosis between the first and second vessels through the opening in the body.

Lyer discloses a prosthetic device for preventing, suppressing or treating failures of hemodialysis vascular access and other vascular grafts, which is usually caused by narrowing (stenosis) at the venous end of the vascular access. The prosthetic device adopts a dual-layered configuration wrapped around the outer surface of a blood vessel for extravascularly delivering therapeutic agents into the vascular wall to suppress the formation of stenosis. Specifically, as illustrated in Figures 7 and 8, and described from Line 65, Col. 10 to Line 20, Col. 11 of Lyer (cited by the Examiner), the inner layer of the Lyer device is made of bioresorbable collagen protein impregnated or saturated with antiproliferative or antistenosis drugs. The antiproliferative or antistenosis drugs absorbed in the inner layer permeate or diffuse through the outer surface of the blood vessel once the prosthetic device is wrapped around the blood vessel to suppress the formation of stenosis within the vessel. The external layer, a PTFE sheet, is a skeletal structure supporting the inner layer. The inner layer and the external layer can be attached with each other using adhesives to form a composite material.

Referring to Figures 3B and 3C of Lyer, the composite material of the two layers is subsequently rolled to form a sleeve, which could be further trimmed to be applied to an artery or vein. In addition, "the free edges of the PTFE sleeve are attached to each other by adhesive, sutures, staples, etc. This stabilizes the entire device on the outside of the vascular structure or

graft" (see, Lines 13-14, Col. 5 of Lyer). The Examiner has cited the above disclosure to assert, "The device is secured via adhesives along its free edges, which would include surfaces for both the first and second vessels. This is viewed as the first and second securing means" (see, Lines 3-6, Page 3 of the Office Action). We believe the assertion is based on the Examiner's improper understanding of Lyer. As illustrated in Figures 2A and 2B, the inner layer 2 is attached to the substantial part of the external layer 5 (PTFE sheet), and free edges of the PTFE sheet are accordingly provided around the inner layer 2 (the white region shown around the inner layer 2). The free edges of the PTFE sheet 5 can be attached with each other by adhesives, which may adjust the size of the sleeve and further stabilize the sleeve on the outside of the vessel. Nowhere does Lyer disclose that the free edges, attached with each other, include surfaces for securing the vessel, contrary to the Examiner's assertion. The above-cited disclosure of Lyer discusses only how to attach the inner layer to the external layer to provide a composite material and how to form a sleeve from the composite material, which can be wrapped around the vessel to deliver drugs for suppressing the formation of stenosis.

Therefore, Lyer does not disclose the first and second securing means, as recited in claim 1. Accordingly, Lyer also fails to disclose the step of adhesively attaching a portion of the first vessel to an extravascular body and attaching a portion of the second vessel to a corresponding portion of the outer surface of the body, as recited in claim 29.

Furthermore, as illustrated in Figures 7 and 8 of Lyer, the prosthetic device (26) provides a drug-eluting sleeve disposed at the intersection of a venous vessel (28) and an arterial vessel (30). Specifically, the sleeve wraps around both vessels to provide a joint-like structure for receiving both vessels within the openings formed within the device. Thus, neither of the

vessels is secured to an outer surface of the device. In contrast, claims 1 and 29 recite that a portion of the second vessel is secured to a corresponding portion of the outer surface of the body, which provides the advantage of directly attaching the device to the second vessel, without wrapping the device around the vessel.

In this regard, the Examiner has reproduced the drawings of Lyer to provide a rim portion, and alleged that Lyer discloses the above distinguishing feature of claims 1 and 29 based on the rim portion (see, page 6 and 7 of the Office Action). Specifically, the Examiner has interpreted the rim portion as a portion of the outer surface of the Lyer device, which is also attached to the second vessel.

Applicants respectfully disagree. As illustrated in the figure at page 7 of the Office Action, the rim portion is identified as the inner portion of the side surface of the Lyer device, adjacent to the second vessel. However, since the second vessel is wrapped around by the device, the side surface of the device does not directly contact the vessel, not to mention that it is not attached to the second vessel via adhesives. Thus, Lyer does not disclose that the second vessel is secured to a corresponding portion of the outer surface of the body.

Since Lyer does not disclose each and every element of the claims 1 and 29, from which all the other claims depend, the rejection of claims 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39 and 41-43 under 35 U.S.C. §102(e) based on Lyer is overcome and withdrawal thereof is respectfully requested.

The Examiner has rejected claims 6 and 40 under 35 U.S.C.§103(a) as allegedly unpatentable over Lyer in view of U.S. Patent Publication No. 2002/0065545 to Leonhardt, et al.(hereafter "Leonhardt"). The rejection is respectfully traversed.

Applicants' independent claims 1 and 29 are discussed above, from which claims 6 and 40 respectively depend.

Lyer is discussed above. Leonhardt discloses a graft, deployable percutaneously by low-profile deployment means and capable of providing a leak-proof conduit through the disease region without suturing or stapling. Leonhardt is relied on to teach a balloon catheter for urging inner members towards outer members. Leonhardt fails to overcome the underlying deficiencies of Lyer. Therefore, neither Lyer or Leonhardt, taken alone or in combination, disclose the combination of features recited in the Applicants' claims. Nor is there any motivation or reasoning in any of the references to combine such features in the references. Accordingly, the rejection of claims 6 and 40 under 35 U.S.C. §103(a) based on the combination of Lyer and Leonhardt is overcome and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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